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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,438	06/23/2003	Andrew Fensome	AHPWA24AUSA	7149
38199 7590 08/27/2007 HOWSON AND HOWSON/WYETH CATHY A. KODROFF SUITE 210 501 OFFICE CENTER DRIVE FT WASHINGTON, PA 19034			EXAMINER HUI, SAN MING R	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 08/27/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/601,438

Applicant(s)

FENSOME ET AL.

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-7,9 and 12-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-7,9 and 12-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2-7-07.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Applicant's amendments filed February 7, 2007 have been entered.

The outstanding rejection under 35 USC 112, first paragraph is withdrawn in view of the amendments filed February 7, 2007.

After the amendments, claims 2-7, 9, 12-14 are pending.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-7, 9, and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 6,355,648 ('648) and US 6,331,562 ('562).

'648 teaches the elected compound and the compounds of formula (I) as useful in inducing contraception (See claims 1-10, 29 and 57, for example).

'562 teaches the compounds taught therein, which are SERMs, as useful in oral contraception (See col. 21, lines 62-63 for example).

The references do not expressly teach the compounds of formula (I) combining with compounds of '562 in a method of inducing contraception.

It would have been obvious to one of ordinary skill in the art at the time of invention to employ both the compounds of '648 and that of '562 in a method of inducing contraception.

One of ordinary skill in the art would have been motivated to employ both the compounds of '648 and that of '562 in a method of inducing contraception.

Concomitantly employing two agents, which are known to be useful for contraception individually, in a method useful for the very same purpose is *prima facie* obvious (See *In re Kerkhoven* 205 USPQ 1069 (CCPA 1980)).

### ***Response to Arguments***

Applicant's arguments filed February 7, 2007 averring no motivation being provided by the cited prior art since there are so many antiprogesterin compounds disclosed in the prior art have been fully considered but they are not persuasive. The examiner notes that the antiprogesterin compounds taught in the cited prior art are almost exactly the same scope as what is recited in the claims. Furthermore, the examiner notes that the elected specie is claimed in claim 57 as useful for inducing contraception. Therefore, possessing the teachings of the cited prior art, one of ordinary skill in the art would have been motivated to concomitantly employ the herein claimed agents together in a method of very same purpose, i.e., inducing contraception, absent evidence to the contrary.

Applicant's arguments filed February 7, 2007 averring no motivation being provided by the cited prior art to combine the herein claimed agents in the instant method have been considered, but are not found persuasive. The examiner notes that the motivation to combine resides on the fact that both agents are useful to induce contraception individually. It flows logically to concomitantly employ both agents in a method of very same purpose, i.e., inducing contraception. The examiner further notes that it is generally acceptable to employ multiple drugs for treating the same condition, barring any drug-drug interaction. For example, treatment for diabetes (insulin with sulfonylurea or metformin), asthma (steroids with  $\beta$ -2 agonist), hypertension (ACE inhibitors with diuretics), cancer (various combination of chemotherapeutic agents), infections (for example cocktail therapy for treating HIV infections), and also oral contraception (estrogen with progesterone). The examples above can be found in

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various fields of medical technology. Therefore, it is generally acceptable to use a combination of agents to treat the very same disease or condition, unless there is some incompatibility recognized in the art.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

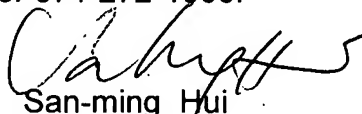
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
San-ming Hui  
Primary Examiner  
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